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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,573	04/19/2000	Gary K. Michelson M.D.	101.0077-00000	3776

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MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,573

Applicant(s)

MICHELSON M.D., GARY K.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-8, 11-34, 36-38, 40-42 and 101-174 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 11-34, 36-38, 40-42, 101-174 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed February 7, 2006, have been fully considered.

Claims 102-106, 108-135, 137-147, 149-168, 172 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (5,888,227).

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Cottle (5,888,227), applicant argues that the first embodiment does not have a configuration wherein the third distance is greater than the first distance; Cottle failed to give a top view of the implant of figure 1 and the Examiner agrees that this limitation is unclear from figures 1-3. However, referring to figure 5 and the teaching of Cottle that a spinal implant can be formed from two semi-implants (see column 4, lines 61 et seq.), it is within the scope of the reference and interpreted by one having ordinary skill in the art, that the implant of figure 5 could be divided backward into two semi-implants. Symmetrically dividing the implant between the front wall 16 and rear wall 15 would produce the claimed limitation. The rejection of claims 102 and 147 and their dependent claims remains; it is the Examiner's position that the width would be less than approximately half of the width of the vertebral bodies and the exterior facing side wall includes a straight portion along element 13 or 14 and meet any intended use language.

Claims rejection under 35 U.S.C. 103(a) as being unpatentable over Williams et al (6,113,638) in view of Brantigan (5,192,327).

It is the Examiner's position that the teaching of **"the implantable device according to the present invention"** being a hemi-device applies to all embodiments

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taught by Williams et al. Referring to at least figure 5A, one skilled in the art would have fully understood that this device could have been built as a hemi-device. At least the spacer portion 116, shown in figure 5D, would have an interior facing side wall.

However, the combination including Brantigan was made to insure side wall for the anchoring portion shown in figure 5F, elements 129, was present. One having ordinary skill would recognize that making a hemi-device of the embodiment of Figure 5A would not destroy the reference; channel 109 would be moved to the middle of each hemi-device. The embodiment of Figure 7 requires the side wall for element 144. Element 144 would have a hollow interior having a maximum dimension between the interior and exterior facing side walls is greater than the maximum dimension of the opening (as required by claim 1, not claims 102 and 147). Forming a hemi-device of the embodiment of Figure 7 would not destroy the device.

Regarding independent claims 102 and 147 requiring the exterior wall facing side including a straight portion, the same applies. It is within the scope of Williams to all embodiments can be hemi-devices.

Claims 1-2, 4-8, 11-34, 36-38, 40-42, and 101-174 (all elected claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Brantigan (5,192,327).

Applicant argues that the Michelson reference already taught the modification of a spinal implant formed in two half device and cannot be modified. The Examiner strongly disagrees. Michelson does not teach the implants 18-23 are hemi-devices as

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stated in column 10, lines 9-16, but only that they are sized to be placed next to each other. Michelson failed to teach the implant like those of figures 1-17 can be formed in half or being less than approximately one-half the maximum width of the adjacent vertebrae. The Brantigan reference clearly states the advantages of forming a "hemi" device.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 102-106, 108-135, 137-147, 149-168, 172 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottle (5,888,227).

Cottle teaches a spinal implant with an asymmetrical leading end 16 which can be formed as either a semi-implant or two-semi implants can be formed integrally; see column 4, lines 61 et seq. Note the exterior facing side wall 13, 14 includes a straight portion.

Copied from the arguments: Referring to figure 5 and the teaching of Cottle that a spinal implant can be formed from two semi-implants (see column 4, lines 61 et seq.), it is within the scope of the teaching and interpreted by one having ordinary skill in the art, that the implant of figure 5 could be divided backward into two semi-implants.

All limitations are self-evident.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-34, 36-42, and 101-174 (all elected claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (6,113,638) in view of Brantigan (5,192,327).

Williams et al teaches various spinal implants which conform to the anatomic contour of the vertebrae comprising an asymmetrical leading end, trailing end, and opposed portions (top and bottom) having at least a non-arcuate portion. Williams further teaches dividing the implant into halves as shown in figure 2 and described in column 5, lines 51 et seq. However, it is unclear upon dividing the implant into halves if an interior facing side wall is formed (and having an inner facing surfaces as only required in claim 1).

Brantigan teaches a similar spinal implant and like Williams teaches the implant can be divide into halves as shown in figure 2 wherein an interior side wall 21c is formed. It would have been obvious to one having ordinary skill in the art to have used the teachings of Brantigan wherein an interior side wall is formed upon dividing the implant in two halves giving better structural integrity and to better contain grafting material.

It is the Examiner's position that the teaching of "the implantable device according to the present invention" being a hemi-device applies to all embodiments taught by Williams et al or at least would have been obvious to one having ordinary skill in the art for the advantage taught in 5:51-6:4. Referring to figure 7A, openings 143 have a dimension less than the maximum dimension between the interior and exterior facing side walls when the device is formed as a hemi-device. Regarding independent claims 102 and 147 requiring the exterior wall facing side including a straight portion, the same applies. It is within the scope of Williams to all embodiments can be hemi-devices; note figures 5A and 7A teaching said limitation.

All other limitations are believed self-evident (or well known in the art).

Claims 1-2, 4-8, 11-34, 36-38, 40-42, and 101-174 (all elected claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Brantigan (5,192,327).

Referring to figures 1-17, Michelson teaches a spinal implant having an anterior aspect, a posterior aspect, and sidewalls. Michelson further teaches opposed surfaces having at least one opening and said opposed surfaces can be relatively angled. Michelson further teaches all claimed surfaces, elements, and material. Michelson teaches an implant having a convex leading end "which may be curved so as to conform to the shape of the vertebral surfaces" and wherein the "upper and/or lower surfaces may be convex and/or front and/or rear surface" (see column 2, lines 23-34).

However, Michelson fails to teach the implant like those of figures 1-17 are formed in half or being less than approximately one-half the maximum width of the adjacent vertebrae.

Brantigan teaches a similarly configured spinal implant which can be formed in a whole configuration, as shown in figure 1, or in two halves, as shown in figure 2. It would have been obvious to one having ordinary skill in the art to have used the teachings of Brantigan to have formed the spinal implant of Michelson which conforms to the shape of vertebral surface in two *halves "for usage in partial corpectomy operations and also side-by-side relation when an intermediate nerve space is needed (see column 4, lines 57 et seq.)"*

It would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER